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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/724,194 KOKAI-KUN ET AL. Office Action Summary Examiner Art Unit GINNY PORTNER 1645 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 03 October 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 18.21-25.28 and 39-58 is/are pending in the application. 4a) Of the above claim(s) 39-58 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 18.21-25 and 28 is/are rejected. 7) Claim(s) 18 is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 01 December 2003 is/are; a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date 10/3/2008

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6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

Claims 18, 21-25, 28, 39-58 are pending.

Claims 18, 21-25 and 28 are under consideration.

Claims 39-58 remain withdrawn from consideration.

# Information Disclosure Statement

The information disclosure statement filed October 3, 2008 has been considered.

### Objections/Rejections Withdrawn

2. Withdrawn, Claim Rejections - 35 USC § 103 Claims 18, 21-25 and 28 rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al (US Pat. 6,939,543, filing date June 2001) in view of Patti (US Pat. 6,703,025, filing date August 31, 1999), is herein withdrawn in light of the claim amendment of independent claims 18 to recite the phrase "Figure 1A".

#### Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Withdrawn, Claims 18 and 24 and 28 rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al (US Pat. 4,954,449) in light of Argaman et al (1974), is herein withdrawn in light of the claim amendment of independent claim 18 to recite the phrase "Figure IA".

#### Claim Rejections - 35 USC § 112

- 9. The following is a quotation of the first paragraph of 35 U.S.C. 112: The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 10. Withdrawn, Claims 18 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a humanized antibody or a humanized single-chain FV (scFV), or fragments thereof comprising both VH and VL domains, wherein the humanized antibody, the humanized scFV, and fragments thereof comprise 6 CDRs, three from the VH domain and three from the VL domain, wherein the humanized antibody, the humanized scFV, and fragments thereof bind the same antigen as the parental non-human antibody. does not reasonably provide enablement for a humanized variable domain, a

humanized antibody, a humanized scFv, and fragments thereof that do not bind to the same antigen and the whole antibody or bind a different antigen than the parental non-human antibody as broadly encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The rejection is herein withdrawn in light of the fact that the claims have been amended to recite a specific antigen structure to which the instant specification teaches monoclonal antibodies which bind to this antigen, and provide guidance for the attainment of additional antigen binding antibodies derived therefrom (binding fragments, recited in claim 25).

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 1 12, first paragraph, have been described by the court in In re Wands, 8 USPQ2d 1400 (CA FC 1988). Wands states on page 1404.

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction of guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skell of those in the art, (7) the predictability or turnefucitability of art, and (8) the beadth of the claims."

Claims 1 and 21-25 and 28 include and are broadly drawn to fragments of the VH or VL domains (see claim 1 "or fragment thereof"), which do not contain a full set of 6 CDRs and does not bind antigen.

Claim 25 includes humanized selv, fragments which need not bind antigen or bind a different antigen than the parent non-human antibody and are interpreted to retain a ścone murine framework residues (i.e., substantial) identical to human framework regions). It is noted that claims 21-24 and 28 are also drawn to a monoclonal antibody, but the claim language encompasses humanized antibody fragments, which do not contain the full set of CDPs and would not bind antigen and the claims do not require that the antibody or fragments, which do not contain the full set of CDPs and would not bind antigen and the claims do not require that the antibody or fragments thereof bind antigen or bind the same antigen as the parental non-human antibody.

The specification discloses only humanized antibodies that contain both a VH and a VL chain and the humanized antibodies bind the same antigen as the parental non-human antibodies, (anti-LTA) (see Examples and Figures). The specification does not enable humanized variable domains, humanized antibodies, humanized servs, and fragments thereof, which do not contain the necessary CDRs that thin dit he same antigen as the whole antibody.

The claims encompass a humanized antibody, a humanized scFv and fragments thereof, which do not contain a full set of CDRs and do not bind antigen or the same antigen as the parental non-human antibody and can retain a/some murine residue(s) in the framework regions (i.e., substantially identical to human framework regions). It is well established in the art that the formation of an intact antigen-binding site of all antibodies requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs or hypervariable regions, which provide the majority of the contact residues for the binding of the antibody to its target epitope (Paul, Fundamental Immunology, 3rd Edition, 1993, pp. 292-295, under the heading "Fv Structure and Diversity in Three Dimensions"). The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity, which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites (Paul, page 293, first column, lines 3-8 and line 31 to column 2, line 9 and lines 27-30). Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al(Proc. Natl. Acad. Sci. USA 1982 Vol. 79: page 1979). Rudikoff et al teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function. It is unlikely that humanized antibody, humanized scFv and fragments thereof as defined by the claims, which may contain less than the full complement of CDRs from the heavy and light chain variable regions have the required binding function. Applicants have provided insufficient evidence or nexus that would lead the skilled artisan to predict the ability of producing a humanized antibody, a humanized scFv and fragments thereof containing fewer the needed number of CDRs to bind antigen, resulting in a humanized antibody that retains the antigen specificity of the parental non-human antibody, Further, a fragment of the light and heavy variable and constant domains can be any one of the CDRs, any one of the constant regions (CH1-3) and also may be the hinge region. However, the claim language also reads on small amino acid sequences, which are incomplete regions of the variable and/or constant region of the antibody. One of skill in the art would neither expect nor predict the appropriate functioning of the antibody as broadly as is claimed.

Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention as it pertains to a method of

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producing a humanized antibody, a humanized scFv and fragments thereof commensurate with the scope of the claims from the written disclosure alone.

## Objections/Rejections Maintained/ Response to Arguments

 Applicant's arguments filed October 3, 2008 have been fully considered but they are not persuasive.

## Maintained, Double Patenting

- 2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, II F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPO 644 (CCPA 1960).
- A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January I, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 3. Maintained, Claims 18, 21-25 and 28 rejected on the ground of nonstatutory obviousnesstype double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,169,903 is traversed on the grounds that the instantly claimed antibodies "would not significantly crossreact with peptidoglycan or lipoteichoic acid (LTA).
- 4. Applicant's traversal has been considered and not found convincing because this combination of claim limitations are not recited in the pending claims and US Pat. 7,169,903, claims 7-10 include antibodies directed to pentidoglycan and lipoteichoic acid that include

monoclonal antibodies directed to N-actylglucosamine and teichoic acids see described embodiments at "[0003] Man has long battled infections caused by bacteria, particularly Grampositive positive bacteria. The surface structures and cell wall of Gram-positive bacteria form a complex matrix that performs functions essential in bacteria and host interactions. The cell wall consists of a peptidoglycan macromolecule (repeating units of N-acetylglucosamine and Nacetylmuramic acid) and attached accessory molecules including teichoic acids, lipoteichoic acids, and carbohydrates (see, e.g., (9) and (24)). In addition, there are many surface proteins anchored to the bacterial cell wall (see, e.g., (17))" which are encompassed by the instant claims are directed to compositions of monoclonal antibodies directed to teichoic acids plus additional carbohydrates and proteins depending on the species and include monoclonal antibodies directed to GleNAc (N-acetylglucosamine ) modification and cross react with WTA from other staphylococcal species "[0041] The term "wall teichoic acid" (WTA), as used herein, includes complex surface-exposed polymers covalently linked to the peptidoglycan in staphylococcal cell walls, WTA also includes soluble whole WTA or fragments thereof. In one embodiment, WTA may be produced synthetically. In another embodiment, WTA may be isolated from staphylococci such as, but not limited to, S. aureus. .... The cell walls of Gram negative bacteria are made up of a unique outer membrane of two opposing phospholipid-protein leaflets, with an ordinary phospholipid in the inner leaflet but the extremely toxic lipopolysaccharide in the outer leaflet. The cell walls of Gram positive bacteria seem much simpler in comparison, containing two major components, peptidoglycan and teichoic acids plus additional carbohydrates and proteins depending on the species. Though the structure of WTA differs between different staphylococcal species, antibodies raised against S, aureus WTA may recognize some common

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WTA modifications such as D-Alanine esters or GlcNAc" (N-acetylglucosamine )

modification and cross react with WTA from other staphylococcal species. Moreover anti-WTA antibodies may also specifically bind non-staphylococcal species. For example, Listeria monocytogenes has the same WTA structure as S. aureus. Thus, antibodies that specifically bind S. aureus WTA may also specifically bind L. monocytogenes.

Though the scope of the allowed claims is not identical to the instant claims, the allowed claims are directed to a genus of compositions that comprise antibodies of the instant claims, the instant claimed being a species of invention encompassed by the allowed genus. The obviousness type double patenting rejection is maintained for reasons of record and responses set forth herein.

### New claim limitations/New Grounds of Objection/Rejection

#### Drawings

- 5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:
- Figure 1A recites the descriptors of "TagO" and "DltABCD" which are not described in the Brief Description of Figure 1A.
- Additionally, [031] refers to "highlighted in gray boxes" (no gray boxes are shown),
- [034] refers to "gray bars" (which are shown as white or black bars).
- [038] refers to "gray triangles" which are only shown in the LL-37 figure, while the other
  two images also have Δ's that are not gray. Corrected drawing sheets in compliance with 37
  CFR 1.121(d), or amendment to the specification to add the reference character(s) in the
  description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to

avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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## Claim Objections

6. Claim 18 is objected to because of the following informalities: Claim 18 has been amended to recite the phrase "Figure 1A". See MPEP section 2173.05(s) Reference to Figures or Tables in the claims should be removed where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. See MPEP § 608.01(m). Appropriate correction is required. Appropriate correction is required.

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## Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
  obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18, 21-25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotz and Peschel (common inventor, DE19912706) et al in light of English translation, in view of Fischer (reference of record, US Pat. 6,939,543, filing date June 2001) in view of Patti (US Pat. 6,703,025, filing date August 31, 1999).

Gotz et al teach and show the chemical structure of the ribitol teichoic acid (see De 19912706, figure 1, Wandteichonsaure) for Staphylococcus aureus strain Sa113 (same strain as the instant Application, see De 19912706 col. 7, line 45) and antibodies directed thereto (see De 19912706 col. 5, line 62 "spezifischen Antiseren", col. 6, lines 28-30 and lines 17-32, col. 6, lines 56-58 and English machine translation). Goetz et al teach antibodies in antiserum ("antiserums, which recognize specific alanine-substituted... Teichonsauren") that specifically bind to the ribitol teichoic acid of Staphylococcus aureus strain Sa113 (Goetz Figure 1 "Wandteichonsaure"), the chemical structure being:

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Goetz et al teach active agents that reduce or inhibit Gram Positive bacterial adherence/infection and biofilm formation (see at least claims 19-26), formulation of compositions for administration, suggests pharmaceutical compositions and polyclonal antibodies directed to the ribitol wall teichoic acid of Staphylococcus aureus but differs from the instantly claimed invention by failing to show the antibodies in the compositions to be monoclonal antibody compositions formulated as pharmaceutical compositions.

Fischer et al teach the importance of producing polyclonal, monoclonal, chimeric, human and humanized antibodies to ribitol phosphate teichoic acids (see col. 5, lines 32-35) in an analogous art for the purposes of producing anti-teichoic antibodies (see col. 22, lines 48-52, col. 5, lines 32-40) associated with Staphylococcal aureus antigens (aureus (see col. 22, lines 30-35 and 48-52), abstract and col. 2, line 2) to increase the opsonization and phagocytosis of S. aureus (see col. 22, lines 30-35 and 48-52).

Patti et al teach the production of antibodies to glycerol or ribitol phosphate in an analogous art for the purposes of producing anti-teichoic antibodies (see col. 22, lines 48-52) associated with staphylococcal antigens (abstract) to increase the opsonization and phagocytosis of S. aureus and to serve as pharmaceutical compositions in treating Staphylococcal infections.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the compositions of Gotz et al to comprise monoclonal antibodies as taught by Fischer et al and to formulate them into pharmaceutical compositions as taught by Patti et al because Patti et al teach anti-ribitol and anti-glycerol teichoic acid antibodies provide for increased opsonization and phagocytosis of Staphylococcus aureus and Fishcer et al teaches ribitol and glycerol teichoic acids are major antigens in the cell was of gram

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positive/Staphylococcal pathogens to include Staphylococcus aureus and monoclonal antibodies are highly specific to the antigen to which they bind and are not dependent on animals for production.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining monoclonal anti-ribitol teichoic acid antibody compositions directed to the S. aureus cell wall antigen of Gotz et al, because Patti et al teaches that through using ribitol phosphate linked to peptidoglycan, the teichoic acids are antigenic and antiteichoic acid antibodies are produced (see col. 22, lines 48-52) and Fischer et al teach and provide motivation for the production of monoclonal antibodies, and recombinant antibodies and fragments specific to ribitol teichoic acid, the anti-ribitol teichoic acid antibodies being means that provides for the generation of vaccines and other therapeutics (see Fischer abstract). Gotz et al in view Fischer and Patti obviated the instantly claimed invention as now claimed.

In re Erlich 1988 teaches that it is obvious to make a monoclonal antibody to an antigen to which a polyclonal antibody is known.

Additionally, KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar element according to known methods is likely to be obvious when it does no more than yield predictable results". It well known in the art to use monoclonal antibodies for formulation of compositions to

a specific ribitol teichoic acid, the guidance and teaching of the references provide a solution to providing a ready source of specific antibodies that maintain their specific binding characteristics, and reduces the dependence upon immunization of animals to produce an antibody containing antisera that would vary upon the immune systems of different animals. Thus, it would be obvious to apply a known technique (monoclonal antibody production) to a known product (generation of antibody containing antiserum specific to ribitol wall teichoic acid) to be used in a known method (generation and formulation of monoclonal antibody compositions) that is ready for improvement of having a ready sources of ribitol specific antibodies for the formulation of pharmaceutical compositions to assist in the treatment of Staphylococcal infections.

#### Conclusion

- The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Various references are being cited to show ribitol teichoic acids and antibodies directed thereto.
- Applicant's amendment necessitated the new ground(s) of rejection presented in this
  Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).
  Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

 Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862.
 The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/ Examiner, Art Unit 1645 December 24, 2008

/Robert B Mondesi/ Supervisory Patent Examiner, Art Unit 1645